

JAN 23 2006

K073018  
Pg. 1 of 2

## 510 (k) Summary of Safety and Effectiveness for Target Positioner

**Manufacturer:**

Address: BrainLAB AG  
Kapellenstrasse 12  
85622 Feldkirchen  
Germany  
Phone: +49 89 99 15 68 0  
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: October 23, 2007

**Device Name:**

Trade name: Stereotactic Target Positioner, Target Positioner for Leksell  
Headring, Stereotactic Counterweight

Common Name: Target Positioner, Counterweight

**Predicate Device:**

**BrainLAB LINAC Hardware (K934657)**

Device Classification Name: Medical charged-particle radiation therapy system (892.5050)  
Regulatory Class: Class II

**Intended Use:**

The Target Positioner is used to position the patient for the stereotactic radiotherapy/  
radiosurgery.

The optional usage of the Stereotactic Counterweight improves the accuracy of patient  
positioning during the treatment by compensating the weight of the Target Positioner after its  
removal.

**Device Description:**

The Target Positioner is a non-invasive mechanical device that consists of an aluminum frame  
and four Target Positioner Carrier Plates made of transparent plastics.

In order to ensure a rigid fixation to different types of Headring respectively to the BrainLAB  
Mask System, various Target Positioners with adapted interface specifications are provided.  
The Target Positioner enables alignment of the planned patient's treatment isocenter with the  
LINAC Isocenter.

Prior to the treatment the Target Positioner has to be removed.

The usage of the Stereotactic Counterweight improves the accuracy of patient positioning during the treatment by compensating the weight of the Target Positioner after its removal.

**Substantial equivalence:**

The Target Positioner has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB LINAC Hardware (K934657).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 23 2008

Mr. Rainer Birkenbach  
Executive Vice President  
BrainLAB AG  
Kapellenstraße 12  
85622 Feldkirchen  
GERMANY

Re: K073018

Trade/Device Name: Target Positioner  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: October 23, 2007  
Received: October 25, 2007

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K073018

Device Name: Target Positioner

## Indications For Use:

The Target Positioner (TaPo) is used to position the patient for the stereotactic radiotherapy/radiosurgery.

The optional usage of the Stereotactic Counterweight improves the accuracy of patient positioning during the treatment by compensating the weight of the Target Positioner after its removal.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) *[Signature]*  
Division of Reproductive, Abdominal, and  
Radiological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K073018